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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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June 20, 2005

Re: Docket No. 05D-0106
Draft Guidance for Industry, SLE -- Developing Drugs for Treatment

Abbott Laboratories (Abbott) is pleased to comment on the draft Guidance for Industry, *Systemic Lupus Erythematosus (SLE) – Developing Drugs for Treatment*, published in the *Federal Register* on March 29, 2005.

In general, we find the draft Guidance thorough and thoughtful in its approach. It provides several options for sponsors to evaluate products to treat SLE and specific organ system manifestations of the disease thereby facilitating the development of novel therapies. We have no major objections to the principles contained within the Guidance. We offer the following comments, referenced by the line number where the text appears in the draft guidance, for your consideration when finalizing this Guidance.

Phase 2 Trial Duration (Line 664, Section V.D.5)

The Guidance states, *In general trials should be 12 months in duration although trials of shorter periods can be considered, depending on the organs and outcomes studied.* This statement appears to apply to Phase 3 trials designed to demonstrate efficacy, safety, and duration of response; however, it is not particularly relevant to the design of Phase 2 trials (e.g. proof of concept and dose ranging), where shorter trial durations are the norm. The Guidance should suggest reasonable lengths of times for Phase 2 studies.

Efficacy Endpoints (Line 131, Section III.B and Line 432, Section IV.D)

Throughout the Guidance, FDA recommends that sponsors prospectively define and prespecify efficacy endpoints, but the Guidance does not advise sponsors as to what criteria or definitions are acceptable. For example, at Line 131, Section III.B. *Flare*, FDA recommends prospectively defining *flare*, and at Line 432, Section IV.D. *Reduction in Flares,* FDA recommends that sponsors provide evidence that the chosen definition of *flare* accurately measures clinical flares. Similar statements are made with regard to a clinically meaningful change in a disease activity index. It would be helpful if the Guidance included examples of endpoints/surrogates that are accepted by the Agency.

Should you have any questions, please contact Ms. Lauren Hetrick, Senior Director, Regulatory Intelligence/FDA Liaison Office at (301) 255-0080.

Sincerely,

Douglas L. Sporn
Divisional Vice President